UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Sarah Bergman, Ken Bergman, Patricia Budnik, and Anthony Budnik, Plaintiffs, v. Johnson & Johnson and Ethicon, Inc., Defendants.	Case No. 20-cv-2693 (JRT/JFD) **ORDER ON PLAINTIFFS' MOTION FOR LEAVE TO FILE THEIR SECOND AMENDED COMPLAINT (DKT. NO. 54)**

Plaintiffs Sarah and Ken Bergman and Patricia and Anthony Budnik ("Plaintiffs") bring this personal injury products liability action against Defendants Ethicon, Inc., a corporation responsible for the design, development, and distribution of the pelvic floor repair medical devices at issue in this case, and Johnson & Johnson ("Defendants"), Ethicon Inc.'s parent corporation. The parties are currently in discovery, and this matter is before the Court on Plaintiffs' Motion for Leave to File Their Second Amended Complaint (Dkt. No. 54). This Court held a motion hearing on Monday, September 30, 2021. Andrew Feldman, Esq., from Flint Law Firm, LLC, represented Plaintiffs, and Brandie L. Morgenroth, Esq., from Nilan Johnson Lewis PA represented Defendants. For the reasons set forth below, Plaintiffs' Motion is granted in part and denied in part.

I. Background

A. Allegations in the First Amended Complaint

On November 17, 2003, Dr. Aaron Kirkemo implanted Plaintiff Sarah Bergman with Ethicon's Gynecare TVT and Gynemesh PS pelvic mesh devices. (First Am. Compl.

("FAC") ¶ 2, Dkt. No. 18.) On May 7, 2008, Dr. Michael T. Valley implanted Plaintiff Patricia Budnik with Ethicon's Gynecare Prolift pelvic mesh device. (*Id.* ¶ 6.) Both Plaintiffs subsequently developed medical complications necessitating removal of their implanted devices. (*Id.* ¶¶ 2, 7.)

Because of these complications, Plaintiffs filed this action on December 30, 2020 (Compl., Dkt. No. 1) and the operative pleading on March 19, 2021 (*see* FAC). In their FAC, Plaintiffs asserted fourteen claims against Defendants, including: negligence (Count I); strict liability-design defect (Count II); strict liability-manufacturing defect (Count III); gross negligence (Count IV); negligent infliction of emotional distress (Count V); strict liability-failure to warn (Count VI); breach of warranty (Count VII); fraudulent concealment (Count VIII); constructive fraud (Count IX); common law fraud (Count X); negligent misrepresentation (Count XI); unjust enrichment (Count XII); loss of consortium (Count XIII); and punitive damages (Count XIV). (*Id.* ¶¶ 83–291.)

B. Defendants' Motion for Partial Dismissal

On April 16, 2021, Defendants filed a Motion for Partial Dismissal of Plaintiffs' FAC. (Dkt. No. 22). Chief Judge John R. Tunheim granted in part Defendants' motion on August 13, 2021, holding that Plaintiffs' FAC was deficient because it "failed to include foundational factual allegations and because most of [Plaintiffs'] claims [were] not recognized under Minnesota law." (Mem. & Order at 1–2, Dkt. No. 34.) Based on these deficiencies, the district court dismissed without prejudice 11 claims entirely (Counts II–V, VII–XII, and XIV), and one claim in part (Count I). (*Id.* at 16–17.) Thus, three claims currently remain in the operative FAC: negligence-failure to warn (Count I), strict liability-

failure to warn (Count VI), and loss of consortium (Count XIII). (FAC ¶¶ 83–99, 135–64, 137–44.) Because Plaintiffs wish to reinstate claims previously dismissed under Counts I–II, VIII, and IX–X in this Motion to Amend, the Court will next review Plaintiffs' claims in the FAC and the district court's reasons for dismissing them in whole or part.

1. Negligence (Count I) in the FAC limited to a failure to warn theory

In their FAC, Plaintiffs allege Defendants acted negligently when they

> carelessly and negligently inspected, packaged, trained, manufactured, designed, developed, tested, labeled, marketed, and sold Defendants' TVT, Gynemesh PS, and Prolift products to Plaintiffs, carelessly and negligently concealing the harmful effects of the . . . products from Plaintiffs, and carelessly and negligently misrepresented the quality, safety[,] and efficacy of" those products.

(*Id.* ¶ 85.) Plaintiffs also contend Defendant "fail[ed] to adequately warn or instruct the Plaintiffs and/or their health care providers of known" risks of the TVT, Gynemesh PS, and Prolift products. (*Id.* ¶ 87.)

Chief Judge Tunheim dismissed Plaintiffs' negligent design claim for "fail[ure] to sufficiently allege causation and injury[,]" and Plaintiffs' negligent manufacturing claim for "failure to allege a manufacturing flaw[,]" leaving only a claim for negligent failure to warn. (Mem. & Order at 6, 9.)

2. Strict liability-design defect (Count II) in the FAC dismissed for failure to show proximate causation

In their FAC, Plaintiffs claim Defendants should be strictly liable for design defects in their three mesh pelvic devices at issue because the devices implanted into Ms. Bergman (Gynecare TVT and Gynemesh PS) and Ms. Budnik (Gynecare Prolift) "were not reasonably safe for their intended uses and were defective . . . with respect to their design."

(FAC ¶ 101.) Plaintiffs identified numerous alleged defects in the three medical devices at issue (*See id.* ¶¶ 102–03, 105, 108.) Plaintiffs also identified allegedly safer alternative designs, including "large-pore and light weight polypropylene products, allograft products, and autologous fascia repair devices." (*Id.* ¶ 105.) As a direct result of Defendants' defectively designed mesh pelvic products, Plaintiffs contend that Ms. Bergman and Ms. Budnik sustained pain and suffering, permanent injuries, ongoing medical treatment requirements, and financial and economic loss. (*Id.* ¶ 108.)

The district court dismissed Plaintiffs' strict liability-design defect claim. Chief Judge Tunheim found Plaintiffs had not shown the third element of a strict liability design defect claim, namely, that "the defect was the proximate cause of the injury sustained[,]" because the "FAC lacks basic details about Plaintiffs' alleged injuries, such as when their injuries were discovered, or locations or dates about the revision procedures that Plaintiffs allegedly underwent to address [them]." (Mem. & Order at 7.)

3. Fraudulent concealment (Count VIII), constructive fraud (Count IX), and common law fraud (Count X) claims in the FAC dismissed for failure to meet Federal Rule of Civil Procedure 9(b)'s heightened pleading standard

In their FAC, Plaintiffs pleaded that a relaxed pleading standard for Federal Rule of Civil Procedure 9(b) applies to their three alleged fraud-related claims because Defendants made numerous omissions and misrepresentations; the relevant facts are in Defendants' exclusive knowledge and control; and the fraud occurred over an extended period. (FAC

¶¶ 188, 208, 225.)[1] Plaintiffs claim they and their physicians relied on Defendants' false and inaccurate information about the TVT, PS, and Prolift products in selecting these devices for implantation. (*Id.* ¶¶ 206, 244–46). As a result of this reliance, Plaintiffs Bergman and Budnik allegedly sustained injuries from their implanted devices that include "severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic damages." (*Id.* ¶¶ 223, 246.)

The district court found that Plaintiffs had failed to allege specific facts about the "who, what, where, why, and how" of Defendants' allegedly fraudulent acts that caused Plaintiffs' injuries under these three fraud-based claims, thus failing to meet Federal Rule of Civil Procedure 9(b)'s requirement that parties must plead fraud-based claims with particularity. (Mem. & Order at 11–12 (citing *Tuttle v. Lorillard Tobacco Co.*, 118 F. Supp. 2d 954, 963 (D. Minn. 2000) (describing the heightened pleading requirements of Rule 9(b))).) Chief Judge Tunheim found that this failure was not because Plaintiffs' facts reside "peculiarly within the opposing party's knowledge," which would permit Plaintiffs to meet a relaxed Rule 9(b) standard. (*Id.* at 12–13 (citing *Select Comfort Corp. v. Sleep Better Store, LLC*, 796 F. Supp. 2d 981, 985 (D. Minn. June 17, 2011)) (stating the relaxed Rule 9(b) standard).)[2]

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[1] Plaintiffs also claim that Dr. Aaron Kirkemo, Ms. Bergman's implanting physician, has been an employee of Ethicon since 2008 and, thus, questions of fact exist about his participation in Ethicon's fraudulent actions. (*Id.* ¶ 200, 222.)

[2] Despite the district court's Memorandum and Order, Plaintiffs' SAC continues to assert facts "upon information and belief." (*See, e.g.,* SAC ¶ 251 ("Upon information and belief, on several occasions . . . Defendants' agents, employees, and representatives provided Plaintiff[s'] implanting physicians with false or inaccurate information regarding the relevant risks, adverse events, and contraindications regarding the TVT, Gynemesh PS,

C. Defendants' Motion to Sever

Defendants' Motion to Sever (Dkt. No. 40) is currently pending before this Court, and an Order will issue simultaneously with this Order. (*See* Dkt. No. 69.)

D. Plaintiffs' Motion for Leave to File Their Second Amended Complaint ("SAC")

Plaintiffs now move for leave to file a SAC "to cure the alleged deficiencies identified by the [District] Court." (Pls.' Mot., Dkt. No. 54.) Plaintiffs seek to rehabilitate their negligent design defects claim (Count I) and strict liability design defects claim (Count II) by pleading new factual allegations showing that Defendants' defective mesh pelvic products proximately caused Plaintiffs' alleged injuries. (Pls.' Mem. Supp. at 3–5, Dkt No. 56.) Plaintiffs also seek to rehabilitate the three dismissed fraud-related claims—fraudulent concealment (Count VIII), constructive fraud (Count IX), and common law fraud (Count X)—by adding new factual allegations showing the "who, what, where, why and how" of the Defendants' alleged fraud as it relates to the Plaintiffs' injuries required by the heightened pleading standard of Federal Rule of Civil Procedure 9(b). (*Id.* at 7–8.) Finally, Plaintiffs expressly withdraw their claims for strict liability-manufacturing defect (Count III), gross negligence (Count IV), negligent infliction of emotional distress (Count V), breach of warranty (Count VII), negligent misrepresentation (Count XI), unjust enrichment (Count XII), and punitive damages (Count XIV). (Pls.' Mem. Supp. at 4, 6–8.)

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and Prolift products.").) Based on the district court's findings and Rule 9(b), such allegations remain inadequate.

II. Applicable Legal Standards

Federal Rule of Civil Procedure 15(a)(2) provides that "a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). But the right to amend is not absolute. *Sherman v. Winco Fireworks, Inc.*, 532 F.3d 709, 715 (8th Cir. 2008). Leave to amend may be denied for "compelling reasons such as undue delay, bad faith, or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment." *Id.* (citing *Moses.com Sec., Inc. v. Comprehensive Software Sys., Inc.*, 406 F.3d 1052, 1065 (8th Cir. 2005)). At issue here is whether Plaintiffs have failed to cure the deficiencies of their FAC in their SAC, rendering their amendments futile.

A proposed amendment to a complaint is futile if "the amended complaint could not withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Cornelia I. Crowell GST Tr. v. Possis Med., Inc.*, 519 F.3d 778, 782 (8th Cir. 2008). Rule 12(b)(6) requires dismissal when a complaint fails "to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The plaintiff need not plead "detailed factual allegations," but mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Id.* For a claim to be facially plausible, the plaintiff must allege "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In applying this standard, the Court accepts the factual

allegations as true and views them most favorably to the Plaintiff. *Hager v. Ark. Dep't of Health*, 735 F.3d 1009, 1013 (8th Cir. 2013).

In addition, Rule 9(b) of the Federal Rules of Civil Procedure requires that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." A pleading alleging fraud must identify the "who, what, where, when and how" of such fraudulent acts. *Bank of Montreal v. Avalon Capital Grp., Inc.*, 743 F. Supp. 2d 1021, 1028 (D. Minn. 2010) (citing *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 550 (8th Cir. 1997)); *see also United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006) (noting Rule 9(b) requires facts about the time, place, content, and results of a defendant's fraudulent acts). "The purpose of Rule 9(b) is to provide the defendant with notice of and a meaningful opportunity to respond specifically to charges of fraudulent conduct by apprising the defendant of the claims against it and the facts upon which the claims are based." *In re Hardieplank Fiber Cement Siding Litig.*, No. 12-md-2359, 2013 WL 3717743, at *6 (D. Minn. July 15, 2013) (citing *Commercial Prop. Invs., Inc. v. Quality Inns Int'l, Inc.*, 61 F.3d 639, 644 (8th Cir. 1995)). "Conclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." *BJC Health Sys. v. Columbia Cas. Co.*, 478 F.3d 908, 917 (8th Cir. 2007).

III. Discussion

Defendants raise no challenge to Plaintiffs' design defect or failure to warn claims alleged in the SAC under theories of negligence and strict liability (Counts I and II). (Defs.' Mem. Opp'n at 3 n.1, Dkt. No. 62.) However, Defendants argue the Court should deny

Plaintiff leave to amend their negligence and fraud-based claims because of Plaintiffs' repeated failure to cure deficiencies by amendments previously allowed and because the proposed amendments are futile. (Defs.' Mem. Opp'n at 2 (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)) (stating reasons why a court may deny a motion for leave to amend).) Specifically, Defendants contend that: (1) the proposed amendments to Plaintiffs' negligence claim in Count I still appear to reassert the uncured manufacturing defect claim that Chief Judge Tunheim dismissed; and (2) the proposed amendments to Plaintiffs' three fraud-based claims still fail to meet Federal Rule of Civil Procedure 9(b)'s heightened standard for particularity in pleadings. (Defs.' Mem. Opp'n at 1.) The Court will take each of these arguments in turn.

A. The SAC's Negligence Claim (Count I)

Defendants argue that Plaintiffs' FAC included a now-dismissed negligent manufacturing theory which Plaintiffs reallege in their SAC without sufficient facts to make such a theory plausible under *Twombly*/*Iqbal*. (*Id.* at 2–3, 4.) Specifically, Defendants point out that the SAC retains the FAC's language at paragraph 93 ("Defendants carelessly and negligently inspected, packaged, trained, **manufactured**, designed, developed, tested, labeled, marketed, and sold Defendants' . . . products to Plaintiffs . . ."") and paragraph 101.b ("Defendants' . . . products are defective because they . . . represented: . . . the **manufacture** of the TVT, Gynemesh PS, and Prolift products so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including the Plaintiffs . . ."). (SAC, ¶¶ 93, 101.b (emphases added).) Plaintiffs confirmed at the September 30 hearing that they are *not* pursuing a negligent manufacturing defect claim,

and that any factual allegations made in the SAC are intended to support *only* claims for negligent design defects, negligent failure to warn, and strict liability for design defects. To the extent that Plaintiffs use the verb "manufactured" in paragraph 93, the Court is unsure how Plaintiffs will marshal this fact to support their design defect and failure to warn claims. Likewise, to the extent that Plaintiffs describe Defendants' alleged inaccurate representation of their manufacture of these products as producing a safe—rather than unreasonably risky—product in paragraph 101.b, this appears to focus on how Defendants marketed their product, not how they manufactured it, although the phrasing is confusing. These observations aside, the Court understands the facts pleaded in these paragraphs will be subsumed into Plaintiffs' design defect and failure to warn claims as per Plaintiffs' oral arguments on this Motion. Therefore, the Court finds no dispute between the parties that requires the Court's resolution on this point.

Defendants also argue that Plaintiffs' negligence claims should be limited to only negligent design defect and failure to warn claims, and may not allege negligent actions other than design defect or failure to warn. (Defs.' Mem. Opp'n at 4 n.4.) Defendants specifically point to Plaintiffs' proposed SAC allegations that "Defendants carelessly and negligently inspected, packaged, trained, . . . tested, labeled . . . and sold" the TVT, Gynemesh PS, and Prolift products, and "failed to monitor" and to "conduct post-market vigilance" on their use outcomes. (Defs.' Mem. Opp'n at 3 (citing SAC ¶¶ 93–97).) Defendants argue that these negligence verbs are not recognized causes of action in Minnesota, citing to *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517 (D. Minn. 1989), which held that "Minnesota law has traditionally recognized three causes of action based

on negligence in products liability cases: negligent design, negligent manufacture and negligent failure to warn." *Id.* at 1527. (Defs.' Mem. Opp'n at 3–4.)

Kociemba poses no barriers to the negligent design defect and failure to warn claims that Plaintiffs advance for several reasons. Unlike here, *Kociemba* dealt with jury instructions. The *Kociemba* court was specifically concerned with the language on a special verdict form, which asked the jurors to decide "whether [defendant's] negligent failure to test caused plaintiff's injuries." *Kociemba*, 707 F.Supp. at 1527. The court found the special verdict form wrongly *conflated* the duty to test with the duty to design and manufacture a product safely, and to provide an adequate warning of dangers inherent in its use. *Id.* at 1527. Because of that conflation, the court granted defendant's motion for judgment notwithstanding the verdict. *Id.* at 1528. As discussed below, Defendants in this case do not allege that the SAC wrongly conflates duty to test with the duties to design and manufacture a product safely, or to adequately warn of dangers in its use, and to that degree, *Kociemba* is inapposite.

Additionally, the *Kociemba* court did not hold that failure to test cannot be alleged; it anticipated that it could be, holding, "[t]he duty to test is a subpart of the other three duties because a breach of the duty to test cannot by itself cause any injury." *Id.*; *see also Willmar Poultry Co. v. Carus Chem. Co.*, 378 N.W.2d 830, 836 (Minn. Ct. App. 1985) (finding a defendant's failure to test may be evidence of a negligent failure to warn); *Wagner v. Int'l Harvester Co.*, 611 F.2d 224, 229 (8th Cir. 1979) (finding a failure to test may be evidence of negligence under design, manufacture, or failure to warn theories). Where each knot on a string of alleged negligent actions can be subsumed into one of these

three product liability theories, such pleadings do not fail for want of a cause of action under Minnesota law. The question, then, is whether a defendant's failure to test (or other alleged negligent act) led a defendant "to produce a product that is defective in design, manufacture, or warning." *Kociemba*, 707 F.Supp. at 1527.

Here, at the pleading stage, there is no apparent conflation of failure to test (or inspect, package, train, label, sell, monitor, or conduct post-market vigilance) with any of the recognized theories of negligence under Minnesota law, because Plaintiffs confirmed during the September 30 hearing that they are pursuing design defect and failure to warn negligence theories. (*See* SAC ¶¶ 93–97.) These actions appear plausibly amenable to subsumption under Plaintiffs' defective design or failure to warn claims. Thus, the Court finds no reason to deny Plaintiffs' motion to amend as to the negligent defective design or failure to warn claims.

In sum, because Plaintiffs do not allege negligent manufacturing, but do allege negligence causes of action that can be subsumed under the defective design and failure to warn theories they advance, the Court does not find that Plaintiffs' negligence claims under Count I demonstrate a "repeated failure to cure deficiencies by amendments previously allowed." *Sherman*, 532 F.3d at 715 (citation omitted). Nor have Defendants shown the amendments are futile. Finding that justice so requires this amendment of the Plaintiffs' pleadings as to the negligence claims under Count I and strict liability-design defect claim under Count II, the Court grants Plaintiffs' motion to amend as to these claims. Fed. R. Civ. P. 15(a)(2).

B. The SAC's Fraud-based Claims: Fraudulent Concealment (Count VIII), Constructive Fraud (Count IX), and Common Law Fraud (Count X)

Defendants argue that the proposed amendments to Plaintiffs' three fraud-based claims still fail to meet Federal Rule of Civil Procedure 9(b)'s heightened standard for particularity in fraud-based pleadings—the same failure identified by the district court in dismissing these claims. (Defs.' Mem. Opp'n at 1, 4–8.) Under 9(b), Plaintiffs must plead fraud with particularity, including such nonconclusory "facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *United States ex rel. Joshi*, 441 F.3d at 556. Defendants contend "Plaintiffs add very few substantive allegations, and instead, merely tack on more conclusory assertions[,]" thereby rendering the proposed amendment of these claims futile. (*Id.* at 5.)

Plaintiffs argued at the September 30 hearing that, in analyzing the sufficiency of their fraud-based claims in the SAC, the Court should view the complaint as a whole to find the SAC sufficiently particular, citing to *Shanghai Foretex Fashion Co. v. Wes & Willy, LLC*, No. 8:14CV106, 2014 WL 12605521, at *1 (D. Neb. July 29, 2014) ("Read as a whole, the complaint alleges 'the who, what, when, where, and how' . . . sufficient to withstand a Rule 9(b) motion."). *Id.* (citation omitted). This does not appear to be an accepted legal standard to analyze motions to amend facing a futility argument under Rule 9(b) in this Circuit, and even if it were, the Court finds that the instant pleadings could not be saved by even such a generous standard.

The question before the Court is whether Plaintiffs' SAC now alleges "specifics about the 'who, what, where, why, and how' of the Defendants' alleged fraud as it relates

to the Plaintiffs[’] injuries[.]” (Mem. & Order at 12.) The Court finds that Plaintiffs have not cured the FAC’s deficiencies in the SAC’s pleadings of the three fraud-based claims, and Defendants have not been put on sufficient notice of the charges of fraudulent conduct. *See In re Hardieplank*, 2013 WL 3717743, at *6.

First, the SAC pleads new, high-level allegations that specific employees of Defendants emailed, or potentially received emails, showing Defendants knew or should have known about problems with the TVT, PS, and Prolift devices. (*See* SAC ¶¶ 200, 223, 246 (a Johnson & Johnson employee suggests language to elide discussing common problems with polypropylene); *id.* ¶¶ 201, 224, 247 (a Gynecare employee sends an email to an unspecified entity suggesting the removal of information on dyspareunia complications after the release of an unfavorable study); *id.* ¶¶ 202, 225, 248 (an Ethicon employee emails other Ethicon employees requesting that an FDA Public Health Notification not be distributed and noting the Field Sales organization was not to proactively discuss the notice).)

However, none of these facts show a causal connection between Defendant’s allegedly fraudulent acts and Plaintiffs’ injuries. Even though it seems commonsensical that an inference of fraud follows from Defendants’ employees actively seeking to suppress information at a high-level about their devices’ propensities to cause some of the very injuries that the Plaintiffs now say they have suffered, Rule 9(b) requires specifics. Here, Plaintiffs allege the *who* of some of Defendants’ information-suppressing actions in these emails, and *what* information Defendants withheld, but Plaintiffs do not allege *how* these withholdings filtered into the specific information that Plaintiffs and their physicians

received from Defendants and relied upon to their detriment. In short, Plaintiffs' amended SAC still fails to allege specifics connecting Defendants' alleged fraud to Plaintiffs' injuries.

Second, the SAC pleads new, non-conclusory facts about Plaintiffs' injuries. (*See* SAC ¶¶ 4–8, 102–08, 132–38, 158–64 (documenting Ms. Bergman's diagnosis and symptoms necessitating surgical removal of her pelvic devices, and her device removal surgery date, surgeon, and hospital); *id.* ¶¶ 13–15, 109–12, 139–42, 165–68 (same for Ms. Budnik).) But the SAC does not connect any of these newly alleged facts to Defendants. Plaintiffs allege *what* harms Plaintiffs suffered, not *what* fraudulent statements Defendants made. And Plaintiffs' *who, why*, and *where* relate to the surgery they underwent to have their pelvic mesh devices removed—not to the *who*, *why*, and *where* of fraudulent statements. Plaintiffs do not allege *how* Defendants' fraudulent actions proximately caused Plaintiffs' injuries and outcomes. Thus, Plaintiffs' amended SAC still fails to connect the specifics of the "who, what, where, why, and how" of Defendants' alleged fraud to Plaintiffs' injuries.

Plaintiffs argued at the September 30 hearing that they have added at least one fact that can withstand Rule 9(b)'s fraud-based pleading standard. They allege that Chris Hofschild, Defendants' sales representative, and Dr. Dennis Miller, Defendants' retained preceptor or key opinion leader, provided Dr. Michael Valley (Ms. Budnik's physician), on or about July 25, 2005, with "false or inaccurate information regarding the relevant risks, or adverse events, and contraindications of the Prolift device." (*Id.* ¶¶ 226, 245). This lone alleged fact cannot hold up the entire weight of a pleading that lacks sufficient

specificity to meet the 9(b) standard for its fraud-based claims. In it, Plaintiffs undeniably allege the *who* and some of the *what*,[3] but the *where*, *why*, and *how* remain hidden. Where was this interaction? Why was this information being shared or sought? How was the false information provided? How was it relied upon by Ms. Budnik's physician in relation to Ms. Budnik's implanted pelvic mesh product? Moreover, this interaction pertains only to Ms. Budnik and her physician, and to the Gynecare Prolift device. There is no similar allegation pleaded pertaining to Ms. Bergman and her physician, or to the Gynecare TVT or Gynemesh PS devices. Defendants, if they are to be charged with fraud, are entitled to know the specific allegations of their fraudulent conduct, and Plaintiffs' SAC does not provide them with that information. *See In re Hardieplank*, 2013 WL 3717743, at *6.

Therefore, the Court finds that Plaintiffs' fraud-based pleadings in their SAC are not cured, that they fail for lack of specificity under Rule 9(b), and that this renders the fraud counts in Plaintiffs' motion to amend futile. Fed. R. Civ. P. 9(b). Because of this failure, the Court need not address arguments regarding the special relationship required to bring a constructive fraud claim.

IV. Conclusion

In sum, the Court finds that justice requires granting Plaintiffs leave to amend their complaint as to their negligence claims under Count I and strict liability-design defect claim under Count II. However, because Plaintiffs have failed to cure the deficiencies of their fraud-based claims under Counts VIII, IX, and X, the Court denies Plaintiffs leave to

[3] When asked about the contents of this inaccurate information during the September 30 hearing, Plaintiffs clarified that the information indicated the pelvic mesh devices do not degrade, contract, or deform after implantation.

amend their pleadings as to these Counts because they do not meet Rule 9(b)'s heightened pleading standard. Fed. R. Civ. P. 9(b).

For all these reasons, **IT IS HEREBY ORDERED** that Plaintiffs' Motion for Leave to File Their Second Amended Complaint (Dkt. No. 54) is **GRANTED** as to the negligence and strict liability-design defect amendments proposed in Counts I and II, and **DENIED** as to the fraud-based amendments proposed in Counts VIII, IX, and X. Plaintiffs shall file an amended pleading in compliance with this Order and with the Court's forthcoming Order on Defendants' pending Motion to Sever (Dkt. No. 40), which is being issued simultaneously with this Order (Dkt. No. 69.).

Dated: October 29, 2021

s/ John F. Docherty
John F. Docherty
United States Magistrate Judge